

JOHNSON & JOHNSON HEALTH
CARE SYSTEMS INC.,

Plaintiff,

v.

SAVE ON SP, LLC,
EXPRESS SCRIPTS, INC., and
ACCREDITO HEALTH GROUP, INC.,

Defendants.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

Civil No. 22-2632 (CCC) (CLW)

**DEFENDANTS EXPRESS SCRIPTS AND ACCREDITO'S OBJECTIONS
UNDER FEDERAL RULE OF CIVIL PROCEDURE 53(f)
TO SPECIAL MASTER ORDER COMPELLING THE
PRODUCTION OF PROTECTED HEALTH INFORMATION**

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TABLE OF CONTENTS

Table of Authorities.....	iii
I. Factual Background.....	2
II. Regulatory Background.....	3
III. Procedural Background	6
A. Standard of Review	9
B. The Ruling That Minimum Necessary Does Not Apply in Judicial Proceedings Is Error.....	10
1. <i>HIPAA’s Minimum Necessary Rule Applies in Judicial Proceedings</i>	10
2. <i>The Order Impermissibly Rewrites HIPAA to Add an Exception to the Minimum Necessary Rule</i>	11
3. <i>The Special Master’s Ruling Renders Half of Subsection (a) Superfluous </i>	12
4. <i>The Special Master’s Cited Authority Is Not to the Contrary</i>	14
C. The Minimum Necessary Rule Applies Because the Disclosure at Issue Was Not “Required by Law”	16
D. JJHCS Has Not Provided Sufficient Information to Meet the Minimum Necessary Rule’s Requirements.....	19

TABLE OF AUTHORITIES

CASES

<i>Anderson v. Zubieta</i> , 180 F.3d 329 (D.C. Cir. 1999)	19, 20
<i>Bostock v. Clayton County, Georgia</i> , 590 U.S. 644 (2020)	12
<i>Burns v. Barnhart</i> , 312 F.3d 113 (3d Cir. 2002)	11
<i>Corley v. United States</i> , 556 U.S. 303 (2009)	13
<i>In MSP Recovery Claims v. Sanofi-Aventis US LLC</i> , No. 2:18-cv-2211, 2023 WL 4562998 (D.N.J. July 14, 2023)	14, 15
<i>In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.</i> , 2022 WL 3211421 (D.N.J. Aug. 9, 2022)	9
<i>Jackson v. Wexford Health Sources, Inc.</i> , No. 3:20-cv-00900, 2022 WL 3644158 (S.D. Ill. Aug. 24, 2022)	15, 16
<i>Kisor v. Wilkie</i> , 588 U.S. 558 (2019)	11
<i>Marx v. Gen. Revenue Corp.</i> , 568 U.S. 371 (2013)	13
<i>Occidental Chem. Corp. v. 21st Century Fox Amer., Inc.</i> , 2022 WL 21296568 (D.N.J. Jan. 11, 2022)	17
<i>Pillsbury v. United Eng. Co.</i> , 342 U.S. 197 (1952)	12
<i>San Francisco v. Environ. Prot. Agency</i> , 604 U.S. ---, 145 S.Ct. 704 (2025)	12
<i>U.S. v. Church of Scientology of Boston</i> , 933 F.2d 1074 (1st Cir. 1991)	21
<i>United States v. Raddatz</i> , 447 U.S. 667 (1980)	10
<i>Vorcheimer v. Philadelphia Owners Assoc.</i> , 903 F.3d 100 (3d Cir. 2018)	19, 20
<i>Walker v. Sun Ship, Inc.</i> , 684 F.2d 266 (3d Cir. 1982)	12
<i>Williams v. Taylor</i> , 529 U.S. 362 (2000)	11, 13
<i>Yates Real Estate, Inc. v. Plainfield Zoning Bd. of Adjustment</i> , 404 F.Supp.3d 889 (D.N.J. July 31, 2019)	19

Yates v. United States, 574 U.S. 528 (2015)13

RULES

Fed. R. Civ. P. 53(f)1, 9, 18

REGULATIONS

45 C.F.R. §164.512(a).....4, 5, 9, 10, 11, 13, 14, 16

45 C.F.R. §164.512(e).....4, 5, 7, 11, 12, 16

45 C.F.R. § 164.1035, 16, 17

45 C.F.R. § 164.5023, 4, 10, 16

INTRODUCTION

On April 7, 2025, Special Master Freda L. Wolfson granted Plaintiff Johnson & Johnson Health Care Systems Inc.'s ("JJHCS") motion to compel Defendants Express Scripts, Inc. ("Express Scripts" or "ESI") and Accredo Health Group, Inc. ("Accredo") to produce protected health information ("PHI") without complying with the Health Insurance Portability and Accountability Act's ("HIPAA") minimum necessary rule. Express Scripts and Accredo object to that portion of the Special Master's Order, under Federal Rule of Civil Procedure 53(f).

As a pharmacy benefit manager ("PBM") and specialty pharmacy, respectively, ESI and Accredo are entrusted with millions of patients' sensitive medical information. ESI's clients, their members, and Accredo's patients expect ESI and Accredo to act as stewards of this PHI. ESI and Accredo pride themselves on their protection of PHI and their strict compliance with HIPAA.

Judge Wolfson's April 7, 2025 Order compels the production by ESI and Accredo of unredacted PHI. In particular, Judge Wolfson ruled that "the 'minimum necessary' standard does not apply in a judicial proceeding." Order at 24, ECF No. 582. Because this is an error of law that would result in the production of significant volumes of unredacted PHI, ESI and Accredo respectfully objects under Rule 53(f).

RELEVANT BACKGROUND

I. Factual Background

Express Scripts is a PBM. PBMs contract with health plans or health plan administrators to assist them in implementing their pharmacy benefit. ESI provides value to its clients by, *inter alia*, helping to lower drug costs and reduce waste and inefficiency in prescription drug spending. ESI also creates pharmacy networks through which its clients' members (*i.e.* insured individuals, or patients) can receive their prescription medications at negotiated discounted rates and processes, or adjudicates, prescription drug claims consistent with its clients' plan designs.

Accredo is a specialty pharmacy that provides medication to patients diagnosed with complex and chronic health conditions, such as cancer, HIV, and multiple sclerosis.

Defendant SaveOnSP, LLC ("SaveOnSP") contracts with Express Scripts¹ to help Express Scripts' clients and their members lower drug costs and reduce inefficiency in prescription drug spending. Specifically, SaveOnSP and Express Scripts enable client health plans to save on expensive therapies manufactured by Janssen and its affiliates (collectively, "J&J"), all while ensuring that these patients have no out-of-pocket cost for these therapies.

¹ Accredo does not have a contractual relationship with SaveOnSP.

JJHCS, a J&J subsidiary, oversees J&J's copay assistance that does not hinge on financial need (as distinguished from Johnson & Johnson Patient Assistance Foundation, Inc., the J&J subsidiary that provides charitable funds to patients with established financial need). This litigation arises from JJHCS's allegations that SaveOnSP's, Express Scripts', and Accredo's work to help health plans and their members save on J&J drugs is actually a "scheme" to "misappropriate" funds.

II. Regulatory Background

HIPAA safeguards PHI by prohibiting covered entities and business associates from "us[ing] or disclos[ing] protected health information, except" according to certain specific exceptions. 45 C.F.R. § 164.502(b). In the narrow circumstances where use or disclosure is permitted, HIPAA establishes the minimum necessary rule:

When using or disclosing protected health information ... a covered entity or business associate must take reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

45 C.F.R. § 164.502(b).

There is no "judicial proceedings" exception to the minimum necessary rule.

Rather, the applicable regulations enumerate only six narrow exceptions:

- (i) Disclosures to or requests by a health care provider for treatment;
- (ii) Uses or disclosures made to the individual . . . ;
- (iii) Uses or disclosures made pursuant to an authorization under § 164.508;

- (iv) Disclosures made to the Secretary . . . ;
- (v) Uses or disclosures that are required by law, **as described by § 164.512(a)**; and
- (vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

45 C.F.R. § 164.502(b)(2)(i)-(vi) (emphasis added). Thus, the minimum necessary rule does *not* apply to disclosures “required by law” under Section 164.512(a). However, the minimum necessary rule *does* apply to every circumstance and situation not listed in this exceptions list – including “judicial proceedings,” which are explicitly governed by Section 164.512(e), a section not listed among the exceptions to the minimum necessary rule.

One exception, Section 164.512(a), *can apply* in judicial proceedings, but it does not exempt judicial proceedings generally from the minimum necessary rule. It provides that covered entities “*may* disclose protected health information in the course of any judicial or administrative proceeding” under certain circumstances – such as in response to “discovery request[s].” 45 C.F.R. § 164.512(e)(1) (emphasis added). Such disclosures are permissible under Section 164.512(a), so long as the following two conditions are met:

- (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.
- (2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

Meeting these conditions does excuse a disclosing party from compliance with the minimum necessary rule. Rather, as the United States Department of Health and Human Services (“HHS”) (the agency tasked with enforcing HIPAA) instructs, covered entities responding to discovery request “must make reasonable efforts to limit” their disclosure “to the minimum necessary to respond to the request.” *FAQs: May a Covered Entity Use or Disclose Protected Health Information for Litigation?* U.S. DEP’T OF HEALTH & HUMAN SERVS (Jan. 7, 2005).²

Thus, meeting the requirements of Subsection (e) is necessary, but not sufficient, to fall within the Section 164.512(a) “required by law” exception. Put differently, the minimum necessary rule does not apply only if the disclosure “is required by law”³ and (as relevant here) the requirements of Subsection (e) are also met. On the other hand, disclosures in response to subpoenas or discovery requests, which are governed by 45 C.F.R. § 164.512(e)(1), still are subject to the minimum

² Available at <https://www.hhs.gov/hipaa/for-professionals/faq/704/may-a-covered-entity-use-protected-health-information-for-litigation/index.html>. See *Kisor v. Wilkie*, 588 U.S. 558, 569-70 (2019) (reaffirming *Auer* deference to an agency’s interpretation of its own regulation) (“[T]he power to interpret its own regulations is a component of the agency’s delegated lawmaking powers . . . Or otherwise said, we have thought that when granting rulemaking power to agencies, Congress usually intends to give them, too, considerable latitude to interpret the ambiguous rules they issue.”).

³ HIPAA defines “required by law” as “a mandate contained in law that compels an entity to make a use or disclosure . . . and that is enforceable in a court of law.” 45 C.F.R. § 164.103. The definition includes a list of examples of authorities that compel the production of particular information, which list does not include requests for production or protective orders.

necessary rule. This is because HIPAA separately governs (1) *whether* a disclosure of PHI is permitted and (2) *which safeguards* must be observed when making that disclosure.

In practice, therefore, covered entities routinely work with each other to meet HIPAA's minimum necessary rule without judicial intervention. HHS has issued frequently asked questions ("FAQs") for health care professionals that make this clear. *See FAQs: Is a Covered Entity Required to Apply the HIPAA Privacy Rule's Minimum Necessary Standard to a Disclosure of [PHI] It Makes to Another Covered Entity?* U.S. DEP'T OF HEALTH & HUMAN SERVS (July 26, 2013)⁴ (explaining that when covered entities do "not agree that the amount of information requested by another covered entity is reasonably necessary for the purpose," HHS expects "both covered entities to negotiate a resolution").

III. Procedural Background

This litigation is governed by a Protective Order. *See* Protective Order (Nov. 22, 2022), ECF No. 62. The Protective Order "is intended to provide protection sufficient to constitute a Qualified Protective Order under HIPAA and the regulations promulgated under its aegis," and to that end is explicitly made pursuant to 45 C.F.R. Section 164.512, Subsection (e). *See id.* § 3.

⁴ Available at <https://www.hhs.gov/hipaa/for-professionals/faq/216/does-minimum-necessary-standard-apply-to-disclosures/index.html>.

Before JJHCS amended its complaint to add Express Scripts and Accredo as defendants, JJHCS served third-party subpoenas on both parties. When Express Scripts and Accredo resisted JJHCS's overbroad subpoena requests, JJHCS filed motions to compel in the Eastern District of Missouri and the Western District of Tennessee. These courts denied the motions in part and granted them in part.

In response to the court orders, Express Scripts and Accredo produced substantial amounts of documents and data—including patient-specific data. Accredo made its production first, redacting all PHI in accordance with HIPAA. Dissatisfied with the redactions, JJHCS asked Accredo to reproduce the patient data with certain fields unredacted. *See* Ex. 1, Nov. 13, 2023 Ltr. from H. Sandick to A. Solinger at 2. Because a HIPAA-compliant Qualified Protective Order was in place, and because JJHCS was able to articulate *why* certain fields were necessary, Accredo was permitted under HIPAA's minimum necessary rule to reproduce the data with these specific fields unredacted. *See* Ex. 2, Dec. 12, 2023 Ltr. from A. Solinger to H. Sandick. Meanwhile, Express Scripts made a production of unredacted PHI as required by an order from the District Court for the Eastern District of Missouri, fulfilling all of its obligations under that order.

Thereafter, Accredo and Express Scripts produced patient data with the precise fields JJHCS had requested unredacted and JJHCS made no requests that Accredo and Express Scripts lift further PHI redactions. Yet almost a year later,

JJHCS demanded that the data be reproduced without any redactions. This time around, however, JJHCS refused to articulate why the additional PHI was necessary. Therefore, this is not a case where the parties negotiated over minimum necessary, as expected by HHS, and were unable to reach a resolution. Instead, JJHCS refused to provide any rationale for its claimed needs, asserting instead that it needed *all* PHI. Consequently, HIPAA's minimum necessary rule prohibits Express Scripts and Accredo from producing the requested data on this record. *See FAQs: May a Covered Entity Use or Disclose [PHI] in Litigation?* U.S. DEP'T OF HEALTH & HUMAN SERVS (July 26, 2013)⁵; *FAQs: May a Covered Entity That Is Not a Party to a Legal Proceeding Disclose [PHI] in Response to a Subpoena, Discovery Request, or Other Lawful Process That Is Not Accompanied by a Court Order?* U.S. DEP'T OF HEALTH & HUMAN SERVS (Jan. 9, 2003).⁶

JJHCS moved to compel the unredacted PHI. On April 7, 2025, Special Master Wolfson granted JJHCS's motion, ruling that HIPAA's "'minimum necessary' standard does not apply in a judicial proceeding" and specifically that it "does *not* apply" in this litigation because of the Protective Order. Order at 24, 23,

⁵ Available at <https://www.hhs.gov/hipaa/for-professionals/faq/704/may-a-covered-entity-use-protected-health-information-for-litigation/index.html>.

⁶ Available at <https://www.hhs.gov/hipaa/for-professionals/faq/711/may-a-covered-entity-not-party-to-legal-proceedings-disclose-information-by-court-order/index.html>.

ECF No. 582 (emphasis in original). Express Scripts and Accredo now object to this order pursuant to Federal Rule of Civil Procedure 53(f).

ARGUMENT

The Special Master’s ruling that HIPAA’s minimum necessary standard does not apply in judicial proceedings was an error of law. The minimum necessary rule applies, in particular, to *this* judicial proceeding, despite the Protective Order. HIPAA’s limited exception to the minimum necessary standard for disclosures “required by law” applies only to disclosures required by law under 45 C.F.R. 164.512(a). That section does not apply here. Under HIPAA, discovery requests and subpoenas do not make a disclosure “required by law.” Accordingly, ESI and Accredo must abide by the minimum necessary rule in responding to JJHCS’s discovery requests. Finally, the Special Master erred by holding, in the alternative, that JJHCS had established a need for *all* PHI fields, even those that are meaningless outside of ESI’s own systems. The Court should correct the Order’s errors of law.

A. Standard of Review

“The court must decide de novo all objections to findings of fact [and] conclusions of law made or recommended by a master.” F.R.C.P. 53(f)(3), (4). “The phrase ‘de novo determination’ ... means an independent determination of a controversy that accords no deference to any prior resolution of the same controversy.” *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, No.

219MD02921BRMESK, 2022 WL 3211421, at *2 (D.N.J. Aug. 9, 2022) (quoting *United States v. Raddatz*, 447 U.S. 667, 690 (1980) (Stewart, J., dissenting)).

B. The Ruling That Minimum Necessary Does Not Apply in Judicial Proceedings Is Error

HIPAA's minimum necessary rule does not contain an exception for judicial proceedings in general. The Special Master's ruling to the contrary contradicts HIPAA's plain language. The ruling also improperly rewrites the regulation by adding an exception to the minimum necessary rule and renders Subsection (a) of Section 164.512 superfluous, an impermissible result.

1. HIPAA's Minimum Necessary Rule Applies in Judicial Proceedings

There exist only six exceptions to HIPAA's minimum necessary rule. A general exception for judicial proceedings is not among them:

- (i) Disclosures to or requests by a health care provider for treatment;
- (ii) Uses or disclosures made to the individual . . .
- (iii) Uses or disclosures made pursuant to an authorization under § 164.508;
- (iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;
- (v) Uses or disclosures that are required by law, **as described by § 164.512(a)**; and
- (vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

45 C.F.R. § 164.502(b)(2)(i)-(vi) (emphasis added).

Section 164.512(a), referenced in the list of exceptions, is distinct from Subsection (e) of that same section, which is titled "Disclosures for judicial and administrative proceedings." Thus, the list of six exceptions does not include

“judicial proceedings.”

HHS – the agency responsible for enforcing these regulations – agrees. HHS has specified that “[w]hen a covered entity is party to a legal proceeding ... [t]he covered entity ... must make reasonable efforts to limit such uses and disclosures to the minimum necessary to accomplish the intended purpose.” *FAQs: May a Covered Entity Use or Disclose Protected Health Information for Litigation?* U.S. DEP’T OF HEALTH & HUMAN SERVS (Jan. 7, 2005).⁷ It was legal error for the Special Master to rule that the “‘minimum necessary’ standard does not apply in a judicial proceeding.” Order at 24, ECF No. 582.

2. The Order Impermissibly Rewrites HIPAA to Add an Exception to the Minimum Necessary Rule

“[T]he basic tenets of statutory construction hold true for the interpretation of a regulation.” *Burns v. Barnhart*, 312 F.3d 113, 125 (3d Cir. 2002) (quotation omitted). “[T]he cardinal principle of statutory construction [is] that courts must give effect, if possible, to every clause and word of a statute.” *Williams v. Taylor*, 529 U.S. 362, 364 (2000). Courts do not have “the power to rewrite” statutes,

⁷ Available at <https://www.hhs.gov/hipaa/for-professionals/faq/704/may-a-covered-entity-use-protected-health-information-for-litigation/index.html>. See *Kisor v. Wilkie*, 588 U.S. 558, 569-70 (2019) (reaffirming *Auer* deference to an agency’s interpretation of its own regulation) (“[T]he power to interpret its own regulations is a component of the agency’s delegated lawmaking powers . . . Or otherwise said, we have thought that when granting rulemaking power to agencies, Congress usually intends to give them, too, considerable latitude to interpret the ambiguous rules they issue.”).

especially if such judicial revisions “make what was intended to be a limitation no limitation at all.” *Walker v. Sun Ship, Inc.*, 684 F.2d 266, 269 (3d Cir. 1982) (quoting *Pillsbury v. United Eng. Co.*, 342 U.S. 197, 2000 (1952)). Therefore, courts may not “add to, remodel, update, or detract from” statutory – or regulatory – language. *Bostock v. Clayton County, Georgia*, 590 U.S. 644, 654 (2020). Nor may courts decide that the drafters “omitted” a term “simply because [they] wanted to save ink or assumed that ... interested parties would understand the omission of the term was inconsequential.” *San Francisco v. Environ. Prot. Agency*, 604 U.S. ---, 145 S.Ct. 704, 714 (2025).

The Special Master’s ruling that the “‘minimum necessary’ standard does not apply in a judicial proceeding” not only departs from the plain regulatory language and HHS guidance interpreting the same, but would effectively rewrite that language by creating an exception to the minimum necessary rule that the drafters did not see fit to include – namely, a general exception for judicial proceedings, currently governed by Section 164.512(e). *See* Order at 23, ECF No. 582. It is thus an error of law that should be reversed.

3. *The Special Master’s Ruling Renders Half of Subsection (a) Superfluous*

The Special Master’s ruling is incorrect for another reason: it renders much of Subsection (a) of Section 164.512 superfluous. “In light of the cardinal principle of statutory construction that courts must give effect, if possible, to every clause and

word of a statute, this Court must give independent meaning to both” sub-parts of Subsection (a). *See Williams*, 529 U.S. at 364. This “canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme.” *Yates v. United States*, 574 U.S. 528, 543 (2015) (“We resist a reading . . . that would render superfluous an entire provision passed in proximity.”) (quoting *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 386 (2013)). Here, the language the Special Master rendered superfluous was not only in the same statutory scheme, but the very same subsection.

The two sub-parts of Subsection (a) are as follows:

- (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.
- (2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

According to the Special Master’s logic, the existence of a Qualified Protective Order under Subsection (e), thus satisfying sub-part (2), is sufficient for the minimum necessary rule to no longer apply. That logic renders sub-part (1) superfluous. *See Corley v. United States*, 556 U.S. 303, 314 (2009) (“[A] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.”).

What Subsection (a) actually provides is that it is necessary, but not sufficient,

for the disclosure to be in a judicial proceeding with a Qualified Protective Order in place under Subsection (e). Still, however, for such a disclosure to be exempt from the minimum necessary rule, there must be *both* such a Qualified Protective Order in a judicial or administrative proceeding *and* the disclosure must be “required by law.” 45 C.F.R. § 164.512(a). As such, the Order’s ruling that the minimum necessary rule does not apply in “judicial proceedings” is error.

4. ***The Special Master’s Cited Authority Is Not to the Contrary***

The Special Master cites two cases to support its ruling that the minimum necessary rule does not apply in judicial proceedings or when a Qualified Protective Order exists. However, neither case made such a holding.

In *MSP Recovery Claims v. Sanofi-Aventis US LLC*, the court ordered the production of PHI. *See* No. 2:18-cv-2211, 2023 WL 4562998 (D.N.J. July 14, 2023). However, at no point did the court hold that “‘the minimum necessary’ standard does not apply to disclosures in response to discovery requests when a qualified protective order exists” – rather, this language is a summary of a litigant’s position. *See id.* at *4. In its Analysis and Findings, the district court correctly explained that “the ‘minimum necessary’ requirement does not apply to ‘uses and disclosures required by law.’” *Id.* at *4. There, the disclosure was required by law not because of the existence of a Qualified Protective Order, but because a *second* order had ordered production. *See id.* at *2, 4. Accordingly, the district court held

that an existing order requiring production (not merely the protective order) made the disclosure “required by law,” and that the minimum necessary rule did not apply. *See id.*

MSP Recovery Claims therefore stands in sharp contrast to Judge Wolfson’s analysis. The *MSP Recovery Claims* court had before it not only a HIPAA-qualified protective order, but also another court order requiring production of documents. *See id.* By contrast, Judge Wolfson was reviewing not an order compelling production, but mere discovery requests unaccompanied by a court order. In this situation, HIPAA dictates that responding parties may produce only the minimum necessary PHI.

Similarly, *Jackson v. Wexford Health Sources, Inc.* did not hold that the minimum necessary rule does not apply when a Qualified Protective Order is in place. *See* No. 3:20-cv-00900, 2022 WL 3644158 (S.D. Ill. Aug. 24, 2022). That court merely entered a Qualified Protective Order; it did not order the production of anything or make any binding interpretations of HIPAA. *See id.* at *1 (“The Court . . . ADOPTS the HIPAA-Qualified Protective Order.”). Moreover, the court correctly noted that a disclosure that is “required by law” must *also* “satisfy the requirements of paragraph ... (e) ... of § 164.512.” *Id.* at *3 (citing 45 C.F.R. § 164.512(a)(1)). The court thus correctly recognized that for the minimum necessary rule not to apply, a disclosure must be *both* “required by law” *and* meet the requirements of Subsection

(e) of Section 164.512. *See id.*

C. The Minimum Necessary Rule Applies Because the Disclosure at Issue Was Not “Required by Law”

The minimum necessary rule must apply unless (1) the disclosure of PHI is “required by law” *and* (2) a Qualified Protective Order is in place, pursuant to Subsection (e). *See* 45 C.F.R. § 164.502(b)(2); 45 C.F.R. § 164.512(a). The second factor – the Qualified Protective Order – is not in dispute. However, disclosure pursuant to discovery requests without a court order, as here, is not “required by law” under HIPAA and, accordingly, ESI and Accredo cannot make a disclosure of PHI without complying with the minimum necessary rule.

HIPAA defines “required by law” as “a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law.” 45 C.F.R. § 164.103. The regulation provides a non-exhaustive list of examples, including “court orders and court-ordered warrants; subpoenas or summons *issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; . . . and statutes and regulations that require the production of information.*” *Id.* (emphasis added). This list does not include requests for production in civil discovery, and each of its items has two key characteristics: (1) it orders the production of specified documents or information and (2) it has its own inherent force of law, and does not

require an independent order for it to operate. *See id.*

There is only one document that might be the source of any requirement at law here: JJHCS's request for production of documents (the "RFPs"). The RFPs, however, cannot be a legal mandate under HIPAA, and the production of PHI here was thus not "required by law." That means, in turn, that the minimum necessary rule continues to apply.

RFPs, governed by subsection (e)⁸ instead of (a), cannot make a disclosure required by law. If it were otherwise, any party to civil litigation could receive unlimited PHI merely by demanding it in discovery. But parties to lawsuits are not courts, and RFPs are not *per se* "enforceable in a court of law." 45 C.F.R. § 164.103 (defining "required by law"). If a litigant wishes to render an RFP enforceable, that litigant must move to compel – and it is the ultimate court order compelling production that renders the disclosure "required by law." *See, e.g., Occidental Chem. Corp. v. 21st Century Fox Amer., Inc.*, No. CV1811273MCALDW, 2022 WL 21296568, at *5 (D.N.J. Jan. 11, 2022) (noting that parties must move to compel to

⁸ Notably, HHS cites subsection (e), not (a), when responding to the FAQ "May a covered entity that is not a party to a legal proceeding disclose [PHI] in response to a ... discovery request ... that is not accompanied by a court order?" *See FAQs: May a Covered Entity Use or Disclose Protected Health Information for Litigation?* U.S. DEP'T OF HEALTH & HUMAN SERVS (Jan. 7, 2005), available at <https://www.hhs.gov/hipaa/for-professionals/faq/711/may-a-covered-entity-not-party-to-legal-proceedings-disclose-information-by-court-order/index.html>. And that FAQ provides that "[t]he covered entity must make reasonable efforts to limit the [PHI] . . . to the minimum necessary." *Id.*

enforce discovery requests and “[u]ltimately,” the decision rests with the court). No such order existed when the Special Master held that the minimum necessary rule did not apply.

The Special Master’s April 7, 2025 Order cannot itself fulfill HIPAA’s “required by law” requirement. The Order did not exist when the Special Master held that the minimum necessary rule did not apply.⁹ Thus, HIPAA allowed disclosure of only the minimum necessary PHI – and thus required an exacting minimum necessary analysis before the disclosure of *any* PHI. In addition, the Order circumvents HIPAA’s minimum-necessary rule’s protections of PHI because, instead of engaging in the rule’s required analysis (*i.e.*, did ESI and Accredo disclose “the minimum [PHI] necessary to respond to” JJHCS’s requests), the Order ruled that it did not apply at all. *FAQs: May a Covered Entity Use or Disclose Protected Health Information for Litigation?* U.S. DEP’T OF HEALTH & HUMAN SERVS (Jan. 7, 2005).¹⁰

⁹ Moreover, Express Scripts and Accredo are entitled to raise objections to the Special Master’s order. *See* Fed. R. Civ. P. 53(f) (“In acting on a master’s order ... the court must give the parties notice and an opportunity to be heard ... The court must decide de novo all objections to conclusions of law.

¹⁰ Available at <https://www.hhs.gov/hipaa/for-professionals/faq/704/may-a-covered-entity-use-protected-health-information-for-litigation/index.html>. *See* *Kisor v. Wilkie*, 588 U.S. 558, 569-70 (2019) (reaffirming *Auer* deference to an agency’s interpretation of its own regulation) (“[T]he power to interpret its own regulations is a component of the agency’s delegated lawmaking powers ... Or otherwise said, we have thought that when granting rulemaking power to agencies,

Thus, no authority existed to make the disclosure of PHI “required by law.” Because an exception to HIPAA’s minimum necessary rule can only exist where *both* the disclosure is required by law *and* the requirements of Subsection (e) are met, the ruling that the minimum necessary rule did not apply was error.

D. JJHCS Has Not Provided Sufficient Information to Meet the Minimum Necessary Rule’s Requirements

The Special Master ruled that “[e]ven if the ‘minimum necessary rule’ were applicable, Plaintiff has provided a legitimate basis for seeking the unredacted” PHI. Order at 24, ECF 528. JJHCS did not even attempt an explanation for all of the categories of PHI at issue, arguing instead that it “cannot anticipate” everything it currently needs and that it would be inconvenient to have to justify each such category. *See* Mot. to Compel Production of Documents Without Redaction at 11, ECF 507. The Special Master therefore could not have reviewed ESI’s and Accredo’s compliance with JJHCS’s discovery requests as HIPAA dictates, i.e., disclosing only the minimum PHI necessary to comply with those requests. *See FAQs: May a Covered Entity Use or Disclose Protected Health Information for Litigation?* U.S. DEP’T OF HEALTH & HUMAN SERVS (Jan. 7, 2005).¹¹

Congress usually intends to give them, too, considerable latitude to interpret the ambiguous rules they issue.”).

¹¹ Available at <https://www.hhs.gov/hipaa/for-professionals/faq/704/may-a-covered-entity-use-protected-health-information-for-litigation/index.html>. *See Kisor v. Wilkie*, 588 U.S. 558, 569-70 (2019) (reaffirming *Auer* deference to an agency’s interpretation of its own regulation) (“[T]he power to interpret its own

“‘[N]ecessary’ means ‘required.’ It is a high standard.” *Vorcheimer v. Philadelphia Owners Assoc.*, 903 F.3d 100, 105 (3d Cir. 2018) (interpreting Fair Housing Amendments Act’s use of “necessary”). “[T]he word ‘necessary,’ without more, is stringent.” *Id.* at 106. It is a higher standard than the general relevancy standard under which the Special Master found JJHCS’s proffered reasons for seeking further PHI disclosure “persuasive.” *See, e.g. Yates Real Estate, Inc. v. Plainfield Zoning Bd. of Adjustment*, 404 F.Supp.3d 889, 919 (D.N.J. July 31, 2019) (distinguishing “necessary” from “generally beneficial or more economical”); Order at 24, ECF No. 582. “When writers wish to tighten or loosen the degree of necessity, they add modifiers. Describing a necessity as ‘absolute,’ ‘logical,’ ‘physical,’ or ‘bare’ constricts the necessity required even more.” *Vorchheimer*, 903 F.3d at 106-07. “Minimum” is just such a qualifier. *See Anderson v. Zubieta*, 180 F.3d 329, 342 (D.C. Cir. 1999) (“‘[M]inimum objective qualifications’ are those objective qualifications that can be shown to be truly required to do the job.”); *accord* MINIMUM, Black’s Law Dictionary (12th ed. 2024) (“Of, relating to, or constituting the smallest acceptable or possible quantity in a given case.”). Thus, “*minimum necessary*” restricts the already-stringent meaning of “necessary.” *See id.*

regulations is a component of the agency’s delegated lawmaking powers . . . Or otherwise said, we have thought that when granting rulemaking power to agencies, Congress usually intends to give them, too, considerable latitude to interpret the ambiguous rules they issue.”).

Moreover, the minimum necessary rule requires a case-specific inquiry, because a party's needs depend on that party's purpose. *See* NECESSARY, Black's Law Dictionary (12th ed. 2024) ("That is needed for some purpose or reason"). To "gauge what is necessary," the Court must first "identify the particular need." *Vorchheimer*, 903 F.3d at 107. Although a requesting party need not necessarily justify its needs on a document-by-document basis, it must at least justify them on a category-by-category one. Organizations are therefore expected "to negotiate a resolution of the dispute as to the amount of information needed." *FAQs: Is a Covered Entity Required to Apply the HIPAA Privacy Rule's Minimum Necessary Standard to a Disclosure of [PHI] It Makes to Another Covered Entity?* U.S. DEP'T OF HEALTH & HUMAN SERVS (July 26, 2013).¹² JJHCS has refused to engage in these negotiations, jumping instead to a motion to compel an unspecified number of fields of PHI, including potentially intrusive patient information, like phone numbers and email addresses.

JJHCS admitted in briefing that it "cannot anticipate at this stage, with any degree of certainty, which types of CHI [Confidential Health Information] it will need." Mot. to Compel Production of Documents Without Redaction at 11, ECF 507. Although it offered certain hypotheticals, it did not provide an explanation for why

¹² Available at <https://www.hhs.gov/hipaa/for-professionals/faq/216/does-minimum-necessary-standard-apply-to-disclosures/index.html>.

it needed each category of PHI it seeks. *See id.* at 12 (discussing member identification numbers, drugs, and diagnoses). JJHCS did not even address all of the fields at issue, and thus cannot have shown that these fields are necessary, let alone that they are the *minimum* necessary. *Cf. U.S. v. Church of Scientology of Boston*, 933 F.2d 1074, 1078 (1st Cir. 1991) (“an investigation of whatever documents ‘might throw light’ on the matter is not ... ‘necessary.’ It might, for example, simply be somewhat helpful.”). Because JJHCS did not even attempt to show why most of the categories of PHI at issue are necessary, it was error to rule that JJHCS had shown that *all* categories were necessary.

Setting aside what JJHCS failed to provide, the Special Master’s analysis fails to meet the requirements of HIPAA’s minimum necessary rule. In reviewing JJHCS’s motion to compel, Judge Wolfson should have analyzed whether ESI and Accredo had disclosed the minimum necessary amount of PHI needed to comply with those discovery requests and, if not, what additional PHI JJHCS needed under that minimum necessary rule. *See FAQs: May a Covered Entity Use or Disclose Protected Health Information for Litigation?* U.S. DEP’T OF HEALTH & HUMAN SERVS (Jan. 7, 2005).¹³ Instead, the Special Master engaged in a high-level, single-

¹³ Available at <https://www.hhs.gov/hipaa/for-professionals/faq/704/may-a-covered-entity-use-protected-health-information-for-litigation/index.html>. *See Kisor v. Wilkie*, 588 U.S. 558, 569-70 (2019) (reaffirming *Auer* deference to an agency’s interpretation of its own regulation) (“[T]he power to interpret its own regulations is a component of the agency’s delegated lawmaking powers . . . Or

paragraph analysis that does not even which specific fields of PHI were at issue. *See* Order at 24, ECF 528. This single paragraph applies not HIPAA's exacting minimum necessary standard, but rather a general relevancy standard. And the analysis is devoid of any consideration of whether anything less than a full disclosure could satisfy JJHCS's needs. Thus, the Special Master did not analyze either *necessary* or *minimum necessary*.

JJHCS's claim that it should not have to abide by the minimum necessary rule because of the risk of being "forc[ed] to return to Court to justify its need for each additional category of information" is baseless. *See* Mot. to Compel Production of Documents Without Redaction at 12, ECF 507. JJHCS need only provide its explanation to ESI and Accredo, which it has refused to do. When JJHCS provided such explanations to ESI and Accredo in the past, ESI and Accredo in turn provided JJHCS with the unredacted PHI that it needed. And even if JJHCS *were* forced to relitigate the issue, there is no HIPAA exception for JJHCS's convenience. HIPAA is not designed for convenience; it is designed to protect patient privacy.

Even if this Court rules against Express Scripts and Accredo, and holds that PHI should be produced, an order specifying *which* PHI must be produced is necessary for Express Scripts and Accredo to comply with HIPAA. Moreover,

otherwise said, we have thought that when granting rulemaking power to agencies, Congress usually intends to give them, too, considerable latitude to interpret the ambiguous rules they issue.").

regardless of what this Court may decide regarding productions, the erroneous ruling that the minimum necessary rule never applies in judicial proceedings should be corrected.

CONCLUSION

For the foregoing reasons, ESI and Accredo respectfully request that this Court reverse the Special Master's order compelling the unredacted production of PHI and hold that HIPAA's minimum necessary rule applies in this litigation.

Respectfully submitted,

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